

U.S. Serial No. 08/594,175

2055/0E203

Exhibit A

**Claims Following October 27, 1997 Amendment**  
**With Present Amendments Underlined and BracketED Where Appropriate**

1. (Twice Amended) A method of preparing a lipid vesicle from alkylammonium fatty acid salts, such that the resulting vesicle is substantive to hair, tissue culture cells, epithelial cells and skin, comprising the steps of:
  - (a) dispersing long chain acyl Nn, Nn-dimethyl-1[v], n-diamino alkyl (A-ADDA) molecules in a buffering solution with a load material for delivery, to form a dispersion, said buffering solution having a pH within a range of between around 3.0 to around 10.0 and an ionic strength less than or equivalent to one molar NaCl; and
  - (b) subjecting the dispersion to high shear processing whereby cationic lipid vesicles containing the load material are realized.
2. The method defined by claim 1, wherein said load material is added to said buffering solution before said A-ADDA is added.
3. The method defined by claim 1, wherein said load material is added to said buffering solution after said A-ADDA is added.
4. (Amended) The method defined by claim 1, wherein said buffering solution utilized in said step of dispersing comprises[includes] H<sub>2</sub>O and said alkylammonium fatty acid salt is a trialkylammonium fatty acid salt.

Exhibit A - (i)

5. (Amended) The method defined by claim 1, wherein said step of dispersing comprises[includes] dispersing with a mechanical homogenizer.

6. (Amended) The method defined by claim 1, wherein said step of dispersing comprises[includes] stirring said A-ADDA and buffering solution at a temperature above that of the melting point of said A-ADDA.

7. (Amended) The method defined by claim 1, wherein said step of dispersing comprises[includes] preparing said buffering solution to have a pH in a range of between 5.5 and 10.5 and an ionic strength of less than the equivalent of 1 molar NaCl.

8. (Amended) The method defined by claim 7[8], wherein the pH of said buffering solution is approximately 7.5.

Claim 9 is canceled.

10. (Amended) The method defined by claim 1, wherein the[further including] a step of dispersing [which includes]comprises preparing said A-ADDA from a molecule of ADDA and a fatty acid at a pH of between [around] 6 [to]and 10.

17. (Amended) The method defined by claim 10, wherein said step of dispersing comprises[includes] preparing behenyl-N-behenamido-N2,N2-dimethyl-propyl-1,3-diamine (B-

Exhibit A - (ii)

BDDP).

18. (Twice Amended) A lipid vesicle substantially comprised of alkylammonium fatty acids salts, wherein the resulting vesicle is substantive to hair, tissue culture cells, epithelial cells and skin, said vesicle formed by a process comprising the steps of:

(a) dispersing long chain acyl Nn, Nn-dimethyl-1[v], n-diamino alkyl (A-ADDA) molecules in a buffering solution to form a dispersion, said buffering solution having a pH within a range of between around 3.0 to around 10.0 and an ionic strength less than or equivalent to 1 molar NaCl; and

(b) subjecting the dispersion of high shear processing whereby cationic lipid vesicles are formed.

19. The vesicle defined by claim 18, wherein said load material is added to said buffering solution before said A-ADDA is added.

20. The vesicle defined by claim 18, wherein said load material is added to said buffering solution after said A-ADDA is added.

21. (Amended) The vesicle defined by claim 18, wherein said buffer solution utilized in said step of dispersing comprises[includes] H<sub>2</sub>O and the alkylammonium fatty acid salt is trialkylammonium fatty acid salt.

Exhibit A - (iii)

22. (Amended) The vesicle defined by claim 18, wherein said step of dispersing comprises[includes] dispersing with a mechanical homogenizer.

23. (Amended) The vesicle defined by claim 18, wherein said step of dispersing comprises[includes] stirring said A-ADDA and buffering solution at a temperature above that of the melting point of said A-ADDA.

24. (Amended) The vesicle defined by claim 18, wherein said step of dispersing comprises[includes] preparing said buffering solution to have a pH in a range of between 5.5 and 10.5 and an ionic strength of less than the equivalent of 1 molar NaCl.

25. The vesicle defined by claim 24, wherein the pH of said buffering solution is approximately 7.5.

Claim 26 is canceled.

33. (Amended) The vesicle defined by claim 18[27], wherein said preparing utilizes a fatty acid comprising[including] behenic acid.

34. (Amended) The vesicle defined by claim 18[27], wherein said step of dispersing comprises[includes] preparing behenyl-N-behenamido-N2,N2-dimethyl-propyl-1,3-diamine (B-BDDP).

35. (Twice Amended) An *in vivo* delivery system for encapsulation and delivery of a material, which material is encapsulated within a lipid vesicle and deliverable upon the occurrence of a triggering condition comprising a change in pH or ionic strength, wherein said lipid vesicle structure substantially comprises an acyl[amino] Nn, Nn-dimethyl-1,n[d]-diamino alkyl chain salt bonded to a fatty acid (A-ADDA) such that a hydrophilic portion of said vesicle is cationic, whereby the resulting vesicle is substantive to hair, tissue culture cells, epithelial cells and skin to enhance to system's ability of deliver said material.

36. The delivery system defined by claim 35, wherein said cationic portion of said vesicle readily adheres to proteins.

37. (Twice Amended) A cationic lipid vesicle comprising a fatty acyl salt of a long chain amide, wherein the stability of said vesicle is controllable by controlling the stability of a salt bridge linking said fatty acyl and amide, such that the resulting vesicle is substantive to hair, tissue culture cells, epithelial cells and skin.

38. The cationic lipid vesicle of claim 37, wherein said salt bridge is controlled by varying at least one of pH and ionic strength of a medium containing said vesicle.

39. (Amended) The system defined by claim 35, wherein the material [may be chosen] is selected from the group consisting of[:] hydrophobic and hydrophilic materials.

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Exhibit A - (v)